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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,784	06/05/2000	MARK DE BOER	DEBOER2	1336

545 7590 01/14/2002

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/554,784	DeBoer et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 29, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-10 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-10 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Claims 1-10 are pending.

2. Applicant's election with traverse of Group I (claims 1-3 and 8) in the response to restriction requirement, filed 10/30/01 (Paper No. 12), is acknowledged.

Upon reconsideration and in view of applicant's traversal, claims 1-10 have been rejoined, and are being examined presently.

3. The specification is objected to because there is no description of the figures. Appropriate action is required.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

It is noted that the certified copy of priority document EPO 97203607.3 filed 11/19/1997 has not been received in the instant application.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims encompass a monoclonal antibody that can bind to the IL12R B2 chain expressed on the surface of human T lymphocytes, wherein said binding prevents IL12R B2 chain mediated STAT4 phosphorylation and/or prevents the IL12R B2 chain from dimerization to the IL12R B1 chain, and pharmaceutical composition thereof. However there is insufficient guidance and direction from the instant specification on how to make or use said antibody. The instant specification describes only one monoclonal antibody (3HT) which binds stimulated CD4+ T cells, binds T cell clone L70 which consistently expresses the IL12R beta chain, and binds HUT78.8 which consistently produces mRNA for the IL12R beta chain. However, the instant

specification provides insufficient guidance regarding the ability of said one monoclonal antibody to bind IL12R beta chain per se, such as an immunoprecipitation experiment by said monoclonal antibody clearly showing immunoprecipitation of the beta chain of the IL12 receptor. Furthermore, the instant specification provides insufficient guidance and direction regarding the ability of said one illustrated monoclonal antibody to prevent IL12R B2 chain mediated STAT4 phosphorylation and/or prevent the IL12R B2 chain from dimerization to the IL12R B1 chain. Furthermore, US Patent 5,831,007 which teaches several non-neutralizing antibodies directed to the beta chain of the IL12 receptor, states in column 24, lines 27-28, that no neutralizing monoclonal antibodies to the IL-12 receptor subunit are currently available. Therefore, neither the instant specification nor the prior art discloses or teaches, respectively, a monoclonal antibody that can bind to the IL12R B2 chain expressed on the surface of human T lymphocytes, whereas said binding prevents IL12R B2 chain mediated STAT4 phosphorylation and/or prevents the IL12R B2 chain from dimerization to the IL12R B1 chain, and pharmaceutical composition thereof. Accordingly, the instant specification does not provide sufficient enablement for claims that recite a method, a product or a pharmaceutical composition that encompasses a monoclonal antibody that can bind to the IL12R B2 chain expressed on the surface of human T lymphocytes, whereas said binding prevents IL12R B2 chain mediated STAT4 phosphorylation and/or prevents the IL12R B2 chain from dimerization to the IL12R B1 chain, as recited by instant claims.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art and the lack of sufficient guidance in the specification, it would take undue trial and error to practice the claimed invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-10 encompass a monoclonal antibody that can bind to the IL12R B2 chain expressed on the surface off human T lymphocytes, whereas said binding prevents IL12R B2 chain mediated STAT4 phosphorylation and/or prevents the IL12R B2 chain from dimerization to the IL12R B1 chain, and pharmaceutical composition thereof. The instant specification describes only one monoclonal antibody that is disclosed to bind the beta chain of the IL-2 receptor. However, the instant specification does not disclose that said antibody has the recited functional limitations of preventing IL12R B2 chain mediated STAT4 phosphorylation and/or preventing the IL12R B2 chain from dimerization to the IL12R B1 chain. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.".

Claims 8 and 9 which encompass a pharmaceutical composition comprising said antibody and claim 10 which encompasses a method for treating autoimmune diseases comprising administering the pharmaceutical composition of claim 8, are also not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for essentially the same reasons as described in the preceding paragraph.

Claims 4-10 which encompass a method or composition or product comprising a combination of said monoclonal antibody and an autoantigen, peptide fragments of an autoantigen, or a modified form thereof, and a method or composition or product comprising a combination of said monoclonal antibody and a second monoclonal antibody. However, the instant specification provides insufficient description of any product, method or composition that encompasses a combination of a specific monoclonal antibody with the recited functional limitations of preventing IL12R B2 chain mediated STAT4 phosphorylation, together with a specific autoantigen or a specific second monoclonal antibody. As discussed above the only specific monoclonal antibody to bind the beta chain of the IL-2 receptor disclosed in the instant specification is not described in combination with any other entity.

Further, the instant specification provides insufficient description of peptide fragments of an autoantigen, or a modified form thereof, being described only in the Summary of the Invention Section of the instant specification, and only in terms of the recited claim language. The instant specification discloses no definition as to the structural basis which would serve as the foundation for a description of a method or composition or product comprising the genus of said peptide fragments of an autoantigen, or a modified form thereof, wherein said genus would retain the desired autoantigenic properties.

Similarly, the instant specification provides insufficient description of a second monoclonal antibody, other than in the Summary of the invention where it is disclosed only in terms of the recited claim language that said second monoclonal antibody is therapeutic and includes monoclonal antibodies to costimulatory molecules on T cells or antigen presenting cells such as CD40, CD40L, CD80 and CD86. The instant specification discloses no definition as to the structural basis which would serve as the foundation for a method or composition or product comprising the genus of said second monoclonal antibody, nor is there disclosed a definition regarding the functional basis which would serve as the foundation for a method or composition or product comprising the genus of said second monoclonal antibody, since the function of said antibodies is described as therapeutic on page 5 of the instant specification,. In view of the lack of a clearly disclosed definition of therapeutic, there is insufficient written description as to which monoclonal antibodies to costimulatory molecules on T cells or antigen presenting cells other than CD40, CD40L, CD80 and CD86, would retain the desired therapeutic properties.

Therefore the instant specification provides insufficient written description for Claims 4-10 which encompass a method or composition or product comprising a combination of said monoclonal antibody and an autoantigen, peptide fragments of an autoantigen, or a modified form thereof, and a method or composition or product comprising a combination of said monoclonal antibody and a second monoclonal antibody.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

8. Claims 6-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 6 and 7 are indefinite in the recitation in line 1 of claim 6 of the phrase "of any one of claims 1 or part thereof", since it is not clear what said phrase means.

B) Regarding claim 7, the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

C) Claim 4 is indefinite in the recitation in line 1 of the phrase " of claim 1 or part thereof", since it is not clear what said phrase means.

D) Claim 5 is indefinite for being in improper Markush format. The Office recommends using the phrase "consisting of" before the first member of the group. See MPEP 706.03(Y).

E) Claims 4-10 are indefinite in their recitation of the phrase "combination" because it is not clear whether said combination represents a mixture, an immune complex, a conjugate, and/or a fusion protein.

F) Claim 9 is indefinite in the relationship of "the heat shock protein" of claim 9 to the components in claim 8, and its base claims 1 and 4. Also, it is not clear if the HSP recited in claim 9 is the autoantigen component of claim 4, nor is it clear how the HSP recited in claim 9 would be a component of claim 1.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to

the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner, Group 1640, Technology Center 1600
January 10, 2002

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